

National Organic Standards Board
Handling Subcommittee Discussion Document
Ion Exchange Filtration Process - Resin Materials
August 2, 2022

Background:

In an [August 27, 2019 memo](#), the National Organic Program requested the NOSB provide recommendations related to the process of ion exchange filtration in the handling of organic products. It has become clear that there is inconsistency between certifiers in how they approve or disapprove this type of process. Some certifiers require only the solutions that are used to recharge the ion exchange membranes be on the National List at § 205.605. Others require that all materials, including ion exchange membranes and resins be on the National List.

The National Organic Program provided clarification to certifying agents in an email sent on May 7, 2019, that nonagricultural substances used in the ion-exchange process must be present on the National List. This would include, but is not limited to, resins, membranes, and recharge materials. Originally, the NOP asked all operations to come into compliance with the statement above by May 1, 2020. However, in response to requests for clarification of NOP's rationale, as well as requests to extend the timeline for implementation, the NOP delayed the implementation date in order to gather more information and requested that NOSB review the issue.

The NOP has determined, and some Materials Review Organizations have agreed, that the ion exchange process is a chemical one, and does affect the food in a way that chemically changes it. This process is different from physical filtration. In the ion exchange process, the liquid run through the process exchanges molecules with the those being held on the surface of the resin. The FDA considers ion-exchange membranes and resins to be secondary direct food additives, since there is an effect on the liquid that is run through this process.

Manufacturers and certifiers who wish to continue allowance of the ion exchange process, disagree with some of the findings of the NOP on this complex issue. The different opinions of the need for resins, recharge materials, and membranes to be present on the National List, as well as how they interact with each other and the liquid filtered through the ion exchange process, is complicated and the NOP therefore asked the NOSB to assess this issue.

A simplified summary of ion exchange, provided in the past from OMRI is as follows:

Ion exchange is based on the principle that a solid mass with immobilized charges can attract the mobile ions of the opposite charge in a fluid media. In practice, this involves a column that is like a large pipe packed with an exchanger, which may be in the form of beads, crystals, gels, or granules. The fluid can pass through, but the ions in solution will be pulled out and held to the exchanger. The process chemically changes the resulting fluid.

Techniques used to produce various sweeteners offer a good example of how the process works. Minerals, salts, proteins, and color bodies occur naturally in grape juice, cane juice, beet juice, and corn syrup. The refinement process seeks to remove these "impurities". They are also naturally present or—in case of color bodies—are formed between naturally present components during heating. These can be removed by a number of techniques. Some are physical, some are chemical, and some use both. However, the use of synthetic cross-linked polymeric resins—such as styrene-divinylbenzene (S-DVB)—to remove certain constituents of

liquids based on their chemical properties is a chemical process. The liquified sweetener stream chemically reacts with the ions present on the ion exchange resin to purify and concentrate the desired sugar (Cantor and Spitz, 1956).

Other processing aids that are considered secondary food additives required petitions in order to be considered. In addition to the filtering / clarifying / fining agents mentioned above, these also included the boiler water additives, antifoaming agents, and certain enzymes. Other additives that are considered 'de minimis' in conventional processing—such as disinfectants and atmospheric gases—also required petitions, reviews, and recommendations to be added to the National List. Ion exchange resins are known to leak from columns and thus become incidental additives in the food.

The Handling Subcommittee presented a discussion document at the Spring 2020 meeting, and presented and voted on a proposal at the Fall 2020 meeting, which recommended that the recharge materials be listed, and the resins not be listed. This vote failed (9 yes, 6 no), and the NOSB requested to keep this as a work agenda item. The Handling Subcommittee then presented a proposal at the Spring 2021 meeting that outlined the complexity of this material but didn't take a stance on whether recharge materials and/or resins should be listed. The Spring 2021 proposal passed with the inclusion of a request on the cover letter for the NOP to engage with FDA on this topic about how FDA categorizes resins – as secondary food additives or food contact substances. The NOP sent a memo to the Board with a summary of the discussions. The findings from this meeting were inconclusive as the FDA expressed that ion exchange resins can be both secondary food additives and food contact substances (determined on a case-by-case basis). A clear result of the meeting between NOP and FDA is that it is dangerous territory for the NOSB to rely on the FDA definitions of secondary food additives and food contact substances to determine whether substances should be listed on the National List, as this would result in substances not on the National List needing to be petitioned and substances that are listed that would not need to be listed.

Since there is consensus on the listing of the recharge materials used in the ion exchange filtration process on the National List (based on the public comments, discussions of previous proposals, and current review practices by certifiers), the Handling Subcommittee decided to decouple the review and recommendation of recharge materials from the resins. The Handling Subcommittee drafted a separate proposal for consideration by the full Board at the Fall 2022 meeting recommending that the recharge materials used in ion exchange filtration be listed on the National List.

Subcommittee Review and Discussion:

The Handling Subcommittee is still evaluating whether resins used in ion exchange must be on the National List.

The 2020 technical report (TR) provides a thorough review of ion exchange filtration and should be referred to for details on this process. It is clear that there is widespread use of ion exchange filtration in organic processing whether it be for removal of off-tastes, heavy metals, or clarification of the final product, among others. Alternatives to ion exchange filtration are not generally available.

As noted in the 2020 TR, ion exchange filtration differs from physical filtration processes in that there is an actual chemical change in the ensuing product due to the recharge materials used in this process.

The question of whether the resins themselves contribute to a change in the final organic product or whether, as food contact substances, they are simply a structure that holds the ions to be exchanged, remains. The 2020 TR states that there are studies that demonstrate that the resins do degrade over

time, however that degradation is generally in terms of their loss of resin activity or efficiency or capacity. In other words, the resins are simply not as good at holding ions to be exchanged and thus need to be recharged sooner than they would when they were new. In some cases, this loss of efficacy may be because of a loss of functional groups that were originally present, however the citations referenced in the TR note that this loss seems to primarily occur during the recharge process. Thus, the loss of those functional groups would not be into an organic product, but rather into the recharge material. The 2020 TR further states that the TR writers found no published studies on the human health effects of the degradation of the resins. Based on the findings of the TR it would seem that the resins act in the capacity of food contact substances and not primarily as direct food additives. However, these same resins can be included under secondary food additives (as defined by FDA). Additionally, in response to previous discussion documents and proposals on this topic no public comments were received that provided scientific evidence that the resins degrade and cause changes in the final product. NOSB is seeking more information on this specific part of the ion exchange filtration process.

Based on past NOP guidance, substances categorized as food contact substances may be used unless explicitly prohibited; whereas if categorized as secondary food additives, then they must appear on the National List. This position comes from a policy statement issued on December 12, 2002, which states:

“Accredited certifying agents, food processors, and food manufacturers have contacted the National Organic Program (NOP) regarding under what conditions synthetic substances used as ingredients in processed food products are subject to review and recommendation by the National Organic Standards Board (NOSB).

7 CFR 205.2 defines ingredient as “any substance used in the preparation of an agricultural product that is “still present” (quotations added) in the final commercial product as consumed.” This definition arose from an April 25, 1995, NOSB recommendation on good manufacturing practices in certified organic handling operations.

The NOP defines “still present” as those ingredients regulated by the Food and Drug Administration (FDA) as food additives permitted for direct addition to food for human consumption under:

1. 21 CFR Part 172, Food additives permitted for direct addition to food for human consumption.
2. 21 CFR Part 173, Secondary direct food additives permitted in food for human consumption: *Except*, That, substances classified by the FDA as food contact substances are not subject to this definition.
3. 21 CFR Part 180, Food additives permitted in food or in contact with food on an interim basis pending additional study: *Except*, That, substances classified by the FDA as food contact substances are not subject to this definition.
4. 21 CFR Part 181, Prior-sanctioned food ingredients: *Except*, That, substances classified by the FDA as food contact substances are not subject to this definition.
5. 21 CFR Part 182, Substances generally recognized as safe.
6. 21 CFR Part 184, Direct food substances affirmed as generally recognized as safe.

The NOP also defines “still present” as those materials approved by the Bureau of Alcohol, Tobacco, and Firearms (ATF) as being acceptable for use by proprietors in the production of alcohol beverages under:

1. 27 CFR Part 24, Section 24.246, Materials authorized for the treatment of wine and juice: *Except, That, substances classified by the FDA as food contact substances are not subject to this definition.*
2. 27 CFR Part 24, Section 24.247, Materials authorized for the treatment of distilling material: *Except, That, substances classified by the FDA as food contact substances are not subject to this definition.*
3. The Brewers Adjunct Reference Manual: *Except, That, substances classified by the FDA as food contact substances are not subject to this definition.*

Accordingly, substances listed in 21 CFR Parts 172, 173, 180, 181, 182, and 184; 27 CFR Part 24; and the Brewers Adjunct Reference Manual, **except those substances classified by the FDA as food contact substances**, must be on the National List of Allowed and Prohibited Substances to be used in the production of an “organic” or “made with organic (specified ingredients or food group(s))” processed product.

Handlers must include in their organic systems plan a list of all synthetic substances to be used in the production of processed products. Each synthetic substance must be identified as an ingredient or a contact substance. Any substance identified as a contact substance must be accompanied by documentation that substantiates the claim.”

This memo was archived when the NOP Program Handbook was created, however it has never been formally rescinded and remains in use by some certifiers.

To aid in evaluation, the NOSB requested that the NOP meet with FDA to inform how resins should be categorized: as secondary food additives or food contact substances. Because food additives are listed on the National List and due to the precedent set by the December 2002 policy memo, we believed this distinction would help us to determine if the resins should be listed or not. This meeting took place on June 7, 2021. Unfortunately, the conclusion was that ion exchange resins can be classified both as food contact substances and secondary food additives and are evaluated on a case-by-case basis, and therefore didn't provide information to guide us in either direction.

The NOSB received a number of public comments on its Spring 2020 discussion document, Fall 2020 proposal, and Spring 2021 proposal with a number of different viewpoints.

Some commenters stated that even though a material might be listed both ways, the fact that they are listed by FDA as a food contact substance, exempts those materials from needing to be reviewed by the NOSB and placed on the National List. Other commenters making the counterargument that if a substance is listed as a secondary food additive, regardless of its listing as a food contact substance, that it is under the purview of OFPA, and the resins would therefore need to appear on the National List.

While there was no compelling evidence in the 2020 TR or public comments that the resins degrade and alter the final organic product, this does not mean that there is no evidence. The quote from OMRI at the beginning of this document refers to ion exchange resins leaking from columns and thus becoming incidental additives. Further research into how and to what extent these resins degrade and whether the degradation occurs during the recharge process or during the food filtration process could help shed light as to whether these resins are strictly in contact with the organic product or are incidental food additives.

On a less technical level, there is a procedural context as well. Since some physical filtration materials are listed and resins are not, there are arguments that there is a disparity in the review of materials.

There is also some disparity as to the level of scrutiny certifiers apply to reviews of food contact substances. Some certifiers require listing all the food contact substances and others may not.

Given all of the above information the below options are being presented. These are essentially the same options that were included in the Spring 2021 proposal.

Option 1: Resins do not need to be listed

In previous comment periods stakeholders expressed concern that a de facto statement that resins do not need to be on the National List leaves a wide-open playing field for any resin to be used. While resins currently being used might be acceptable, the lack of a required review for resins could cause issues in the future with resins that would be less acceptable for use in organic production systems. Allowing resin use without review could provide an unintentional loophole to the requirements of OFPA.

However, since resins are currently being used in organic production this is the least impactful option.

Option 2: Require listing of Resins – Categorically

An alternative to allowing all resins without review would be to create a listing on the National List that includes all resins used in ion exchange filtration (similar to other broad categories on the List). Petitions to the NOSB could be used to annotate this broad listing to exclude problematic resins. This process, however, puts the onus on stakeholders to recognize which resins are being used and to act to exclude particular resins. A petition to remove a resin by annotation takes considerable time and forces the petitioner to provide documentation as to how the resin does not comply with OFPA. While this process is in action the resin would continue to be used. This is opposite the more normal procedures of the NOSB whereby the burden is put on the petitioner to document why something should be added to the List and that substance is not allowed to be used until it is added. In the past, removal of substances already being used from the National List becomes difficult due to economic impacts of that removal.

Option 3: Require listing of Resins – Individually

The final possibility is to require each resin to be added to the National List. This would require a petition for each specific resin, technical reports to be commissioned and reviewed, and for the Board to approve the addition of each resin. This would cause significant disruption to the processing industry since these ion exchange filtration practices are already in use and have been for some time. Without a long phase in period, the requirement of listing currently used resins would cause significant economic harm. There could also be potential health consequences since some of these filtration processes remove heavy metals and other deleterious compounds from organic foods.

Requiring the listing of these resins could cause significant economic impact and disruption of current organic supply chains.

Questions to Stakeholders

1. Has there been new information since the NOP policy statement from December 2002, that would indicate a change in policy position about what types of substances are required to be listed on the National List in accordance with OFPA?
2. Does the fact that resins are listed by FDA as a food contact substance exempt these materials from needing to be reviewed by the NOSB and placed on the National List? If so, why?
3. Does the fact that since resins are listed as a secondary food additive, regardless of their listing as a food contact substance place them under the purview of OFPA and therefore need to appear on the National List. If so, why?
4. How and to what extent do resins degrade? Does the degradation occur during the recharge process or during the food filtration process?

5. Which option listed above (Options 1-3) would you choose and why?
6. Is there another option the NOSB should consider in regard to resins?

Subcommittee vote

Motion to accept the discussion document on ion exchange - resins.

Motion by: Kyla Smith

Seconded by: Mindee Jeffery

Yes: 7 No: 0 Abstain: 0 Recuse: 0 Absent: 1